

# Outcomes of renal artery angioplasty and stenting using low-profile systems

Brian W. Nolan, MD, Marc L. Schermerhorn, MD, Erin Rowell, MD, Richard J. Powell, MD, Mark F. Fillinger, MD, Eva M. Rzucidlo, MD, Mark C. Wyers, MD, Robert M. Zwolak, MD, Daniel B. Walsh, MD, and Jack L. Cronenwett, MD, *Lebanon, NH*

**Objective:** Renal artery percutaneous transluminal angioplasty (RPTA) and stenting (RAS) are accepted therapies for selected patients with renovascular hypertension and chronic renal insufficiency. We evaluated the outcomes and complications of RAS performed by vascular surgeons at our institution with modern low-profile systems.

**Method:** We retrospectively analyzed all RPTA and RAS procedures attempted with the use of low-profile systems from June 2000 to September 2003. Eighty-two patients (96 arteries) with atherosclerotic renal artery stenosis were treated. Indication for treatment was hypertension in 44 (54%) and chronic renal insufficiency in 38 (46%). Technical success, complication rates, clinical success for control of hypertension or renal insufficiency, restenosis, and survival were reviewed with a mean follow-up of 1 year.

**Results:** Ninety-three arteries were treated with stents, three with RPTA only. Primary technical success was 95%, with 98% overall technical success. Major complications occurred in 6.1% and minor complications in 1.2%. Hypertension was improved in 81% at 1 year. Renal function was improved in 23%, stable in 53%, and worse in 24% at 1 year. Restenosis was seen by routine duplex surveillance in 25% at 1 year. Restenosis associated with clinical deterioration and confirmed by angiogram was seen in 10%. The overall 3-year survival was 83%.

**Conclusion:** RPTA/RAS can be performed with low-profile systems with excellent technical success, low complication rates, and clinical outcomes that compare favorably with prior reports. (J Vasc Surg 2005;41:46-52.)

Renal artery percutaneous transluminal angioplasty (RPTA) was introduced by Gruntzig<sup>1</sup> in 1978. Initial reports from uncontrolled studies demonstrated an improvement in blood pressure control in patients with renovascular hypertension, and renal function in patients with chronic renal insufficiency (CRI).<sup>2-4</sup> Technical success of RPTA was poor, however, and restenosis rates ranged from 27% to 100% at 1 year.<sup>5</sup>

In 1991, the use of metallic stents in the treatment of atherosclerotic renal artery stenosis was reported and has since been shown to improve technical success and restenosis rates.<sup>5,6</sup> Of the recently published series, the primary success of renal artery stenting (RAS) ranges from 70% to 100%, with restenosis rates of 13% to 43% at 1-year.<sup>5,7-12</sup>

In the only randomized trial comparing endovascular therapy with surgery, Weibull et al<sup>13</sup> showed that RPTA was preferable to surgery as a first-line therapy for renovascular hypertension. Subsequently, because of lower morbidity and mortality rates, endovascular interventions have become more frequent than operative therapy and may have lowered the threshold for treatment of symptomatic atherosclerotic renal artery stenosis. RAS has been shown to improve or cure hypertension in nearly 80% of patients.<sup>5</sup>

RAS has also been shown to slow the decline in renal function in patients with CRI.<sup>14,15</sup>

The morbidity and mortality of endovascular interventions are lower than operative therapy, but complication rates are still significant. Beek et al<sup>16</sup> reviewed complications of RPTA/RAS in 1997, before the use of low-profile catheter delivery systems. Although some improvements have been made in 0.035-in systems since Beek's series, there was a 10% incidence of "minor" complications, 10% incidence of "severe" complications, and a 16% incidence of "radiologic-technical" complications. In a review of the literature of nearly 1000 patients in 13 series, they found overall complication rates ranged from 10% to 66%.

In early reports, RPTA/RAS used 0.035-in guidewires and 8F guiding catheters for treatment of the renal artery. With the advent of lower profile systems (0.014-in and 0.018-in wires, micropuncture sets, 5F and 6F guiding catheters, ultrathin angioplasty balloons and balloon-expandable stents) and embolic protection, the technique of RAS continues to evolve. These devices offer the theoretical advantage of decreased trauma caused by wires and catheters, including atheroembolic renal failure. This review quantifies the outcomes and complications of RAS done with low-profile systems. We report the results of our initial series of low-profile RPTA/RAS, including technical success, complications, survival, clinical outcomes, and restenosis.

## METHODS

We retrospectively reviewed all patients with angiographically confirmed renal artery stenosis in whom an attempt at RPTA or RAS was performed by vascular sur-

From the Division of Vascular Surgery, Dartmouth-Hitchcock Medical Center.

Competition of interest: none.

Reprint requests: Brian Nolan, MD, Division of Vascular Surgery, Dartmouth Hitchcock Medical Center, One Medical Center Drive, Lebanon, NH 03756 (e-mail: [Brian.Nolan@Hitchcock.org](mailto:Brian.Nolan@Hitchcock.org)).

0741-5214/\$30.00

Copyright © 2005 by The Society for Vascular Surgery.

doi:10.1016/j.jvs.2004.10.027

geons from June 1999 through June 2003. This period includes all cases performed by vascular surgeons at Dartmouth-Hitchcock Medical Center to date, including the initial "learning curve" procedures.

**Patient selection.** Patients with renal artery stenosis were treated in accordance with the American Heart Association (AHA) guidelines.<sup>17,18</sup> Indications included (1) hypertension (systolic blood pressure  $\geq 40$  mm Hg, diastolic blood pressure  $\geq 90$  mm Hg, or both) either resistant to treatment with 3 medications of different classes (including a diuretic), or associated with medication intolerance or a solitary kidney; and (2) chronic renal insufficiency (CRI) (serum creatinine  $\geq 1.4$  mg/dL, according to hospital standards) of unknown etiology.

Arteriography was performed on patients with a clinical indication for therapy in whom a stenosis was identified by a screening duplex scan (86%) or other imaging study such as magnetic resonance arteriography or computed tomographic (CT) arteriography (14%). Duplex criteria used for preoperative screening were a peak systolic velocity (PSV) of more than 200 cm/sec or a renal-aortic ratio (RAR) greater than 3.5.<sup>19</sup> Patients with renal insufficiency were pretreated with 600 mg oral N-acetylcysteine twice the day before the procedure and again the day of the procedure.

Indications for RPTA/RAS were arteriographic stenosis greater than 75% or a pressure gradient across the stenosis of more than 15 mm Hg. Efforts were made to minimize the amount of contrast used ( $<1$  mL/kg non-ionic contrast), particularly in patients with renal insufficiency. Bilateral stenosis was treated during the same procedure if contrast volumes could be maintained near this level. Between June 2000 and June 2003, 96 arteries (3 occlusions, 93 stenoses) in 82 patients were treated: 44 (54%) patients were treated primarily for hypertension, and 38 (46%) were treated primarily for CRI. However, because bilateral disease was more prevalent in those with CRI, more renal arteries were treated for CRI (53%).

**Technique.** Percutaneous access via the common femoral artery was obtained using a micropuncture technique (20-gauge access needle, 0.018-in wire, and 5F sheath) to minimize femoral trauma. A 0.035-in Wholey or J wire was advanced through the sheath into the abdominal aorta. Diagnostic arteriography was performed through a 5F flush catheter. Indications for RPTA/RAS were arteriographic stenosis of more than 75% or a pressure gradient across the stenosis of more than 15 mm Hg.

If renal artery stenosis was confirmed, the 5F sheath was upsized to 6F and a 6F left internal mammary artery guiding catheter was advanced over the 0.035-in wire and positioned at the origin of the renal artery. The patient was administered intravenous heparin (100 U/kg). The 0.035-in wire was then exchanged for a 0.014-in or 0.018-in wire. Embolic protection was selectively used with the Guardwire (Medtronic) temporary occlusion and aspiration system (0.014-in). Indications for embolic protection were typically either a serum creatinine level of 2.0 mg/dL or more or a solitary kidney. The renal artery was selected and the lesion crossed with the low-profile wire.

Critical lesions ( $>75\%$ ) were pre-dilated with a 3-  $\times$  20-mm low-profile monorail Gazelle balloon (Boston Scientific). In arteries with a stenosis of less than 75%, a 4F glide catheter was used to measure the pressure gradient across the lesion. A Tuohy-Borst valve on the end of the catheter allowed wire access to be maintained while the catheter was pulled back across the lesion.

Lesions were preferentially treated with premounted balloon-expandable stents with typical diameters of 5 to 6 mm. We typically size our stents to the diameter of the adjacent healthy renal artery. We do not oversize or over-dilate. Angioplasty alone (4 to 6 mm) was performed in cases where the anatomy was unfavorable for stent placement, such as at bifurcations.

After deployment, a completion arteriogram was performed, and a 4F catheter was used to obtain a pressure measurement across the stent. A residual stenosis ( $\geq 30\%$ ), or pressure gradient ( $\geq 5$  mm Hg) was treated with either repeat angioplasty or a second stent if further coverage of the lesion was required. Femoral closure devices were used preferentially where appropriate.

If the device failed or the patient was not a candidate, heparin was reversed and manual pressure held. Patients who were not on clopidogrel preoperatively were given a 300-mg loading dose and then treated postoperatively for 1 month (75 mg orally per day) along with aspirin, which was continued indefinitely.

Technical success was defined on an intent-to-treat basis as a residual stenosis of 30% or less and a pressure gradient of 5 mm Hg or less. If the artery was successfully treated during the initial procedure, it was considered a primary technical success. If the artery could not be cannulated from the femoral approach but was successfully treated from a brachial approach at the same procedure ( $n = 7$ ), this was also considered a primary technical success. Patients who were brought back for a second attempt at a later date, either for a different approach (eg, brachial) or to limit contrast exposure (or both), were considered a secondary technical success if the artery was subsequently treated successfully.

**Outcomes.** Procedural complications were classified as major or minor in accordance with AHA standards.<sup>17</sup> Follow-up office visits, with review of medication, blood pressure, serum creatinine level (in those with CRI), and renal duplex scan were obtained at 1 month postoperatively and every 6 months thereafter. Results are reported at a mean follow-up of 1 year, unless otherwise stated. Clinical measures of blood pressure and renal function are reported at last follow-up in accordance with AHA standards.<sup>17</sup>

- *Improved blood pressure* was defined as a diastolic pressure of less than 90 and systolic pressure of less than 140 on the same or reduced number of medications. Inability to meet these criteria was defined as a *failure*.
- *Improved renal function* was defined as a 20% or more decrease in serum creatinine level, relative to baseline.

**Table I.** Demographics for 82 patients undergoing renal angioplasty and stent placement according to indication for treatment

	HTN (n = 44)	CRI (n = 38)	P
Age (years)	63 ± 11	75 ± 8	<.001
Male gender	32%	73%	.002
Coronary artery disease	37%	62%	.014
Diabetes	16%	30%	.1
Tobacco	85%	79%	NS
Hypercholesterolemia	58%	68%	NS
Peripheral vascular disease	45%	46%	NS
Abdominal aortic aneurysm	23%	21%	NS
Bilateral renal artery disease	32%	50%	.018

HTN, Hypertension; CRI, chronic renal insufficiency; NS, not significant.

- Renal function was considered *stable* if the serum creatinine level remained within 20% of baseline and *worse* if it increased by 20% or more.

Restenosis was determined by duplex scanning with a velocity criteria of PSV greater than 180 cm/s and a RAR greater than 3.5.<sup>9</sup> Arteriography was performed on patients with duplex velocity criteria for stenosis if they had either an elevated serum creatinine level, recurrent or worsening hypertension, a solitary kidney, or a progressively rising duplex velocity. Survival data were available on all patients through the Social Security Death Index.

**Statistical analysis.** We reviewed patient demographics, comorbid disease, the indication for treatment, preoperative duplex characteristics, procedural details, technical success, complications, clinical success, restenosis, and survival. Discrete variables are presented as proportions and compared with the  $\chi^2$  test. Continuous variables are presented as mean  $\pm$  standard deviation and compared with the Student *t* test. Survival, hypertension response, renal function response, and restenosis were analyzed using Kaplan-Meier life-table methods. The log-rank test was used to compare these outcomes between groups. *P* < .05 was considered statistically significant.

## RESULTS

Patients treated for chronic renal insufficiency were more likely to be older, male, and have coronary artery disease, diabetes, and bilateral disease compared with patients treated for hypertension alone (Table I). Concomitant iliac stent placement for preexisting disease was performed on 5 patients (hypertension, 3 patients; CRI, 2 patients). Concomitant endovascular abdominal aortic aneurysm repair was performed in 1 patient (hypertension).

Preoperative duplex data were available on 78 (81%) of the 96 arteries treated. Arteries treated for renal insufficiency tended to have slightly higher velocities and renal aortic ratios; however, this was not statistically significant (Table II).

Most lesions (82%) were ostial or within the proximal 5 mm of the main renal artery. Angiographic stenosis was

**Table II.** Characteristics of 96 renal artery stenoses by duplex and arteriography according to indication for treatment  $\pm$  SD

	HTN (n = 45)	CRI (n = 51)	P
Duplex			
Peak systolic velocity (cm/sec)	295 ± 85	344 ± 187	.11
Renal-aortic ratio	4.1 ± 2.0	5.0 ± 2.8	.1
Arteriogram			
Ostial location	86%	96%	.11
Systolic pressure gradient (mm Hg)	54 ± 34	56 ± 36	NS
Contrast volume (mL)	106 ± 57	69 ± 45	.002

HTN, Hypertension; CRI, chronic renal insufficiency; NS, not significant.

critical (>75%) in 49 arteries. These were treated without first obtaining a pressure measurement across the lesion. Pressure measurements were obtained in the remaining 47 arteries. The mean pretreatment systolic pressure gradient (aorta-to-renal artery) was 55 mm Hg and was similar for both indications. Mean contrast volume used for the procedure was 106 mL (range, 40 to 320 mL) in the hypertension group and 69 mL (range, 15 to 200 mL) in the renal insufficiency group (Table II).

Stents were placed in 93 arteries (97%). A variety of stents were deployed, including the NIR Royal, 60% (Medinol, Ltd), Corinthian, 19% (Cordis Endovascular), Genesis, 9% (Cordis Endovascular), Herculink, 5% (Guidant), and others, 7%. Five arteries were treated with two stents. Six arteries in 4 patients (hypertension, 3; CRI, 1) received PTA alone. Embolic protection was used in 26 arteries (27%).

**Technical success.** Overall primary technical success was 95%. Primary technical success was achieved in all patients treated for hypertension and 88% of patients treated for CRI. Technical failure in all cases was due to an inability to select the renal artery, usually because of acute caudal angulation. These 5 patients with CRI were brought back at a later date and underwent subsequent attempts via the left brachial artery, 4 of which were successful (secondary technical success at 98%).

**Complications.** Complications occurred in 6 patients (Table III). One minor complication (1.2%), a groin hematoma, did not require operative therapy or blood transfusion but did prolong hospital stay by one day for observation. There were five major complications (6.1%). Postoperative azotemia (serum creatinine increase > 20%) occurred in 3 patients (3.9%). Azotemia resolved spontaneously in 1 patient and in another after a stent was placed in a contralateral stenosis on postoperative day 1. Acute renal failure developed in 1 patient with a baseline serum creatinine level of 2.5 mg/dL after a failed attempt at stenting via femoral access. A stent was subsequently placed via a left brachial approach, but the patient did not improve and went on to require dialysis. None of these patients who developed azotemia had embolic protection.

**Table III.** Complications in 82 patients undergoing renal angioplasty and stenting

	<i>n</i>	%
Minor complications	1	1.2
Groin hematoma	1	1.2
Major complications	5	6.1
Azotemia	3	3.7
Perinephric hematoma	1	1.2
Myocardial infarction	1	1.2

One patient developed a perinephric hematoma from a parenchymal perforation with a guidewire. This was detected by CT scan after the patient reported flank pain postoperatively. The patient was transfused with 2 units of packed red blood cells and was discharged on postoperative day 5 without further incident. One patient had a myocardial infarction and required urgent PTA of a coronary artery bypass graft stenosis. There were no perioperative deaths and no operative conversions.

**Length of stay.** Early in the experience, patients were observed overnight prior to discharge. Patients were later selectively observed for postoperative creatinine and blood pressure changes. The mean length of stay was 1.3 days in the hypertension group (range, 0 to 9) and 2.2 days for patients in the CRI group (range, 0 to 12).

**Survival.** By life-table analysis, overall 3-year survival was 83%. Three-year survival was 86% for patients treated for hypertension and 81% for patients treated for CRI. These differences were not statistically significant.

**Hypertension response.** Follow-up data on blood pressure and renal function were available on 83 (98%) of 85 patients. In those patients treated for hypertension, mean systolic pressure, diastolic pressure, and need for antihypertensive medication significantly decreased (Table IV). Although patients with CRI were not treated primarily for hypertension, 66% were hypertensive. Follow-up blood pressure data were available on 32 (86%) of these patients and showed statistically significant decrease in diastolic pressure and medication requirements (Table IV). At 1 year, 81% of patients had blood pressure improvement as defined by AHA criteria (Fig 1).

**Renal function response.** The mean baseline serum creatinine level was 2.1 mg/dL for all patients with CRI. Baseline creatinine was slightly higher in patients who received embolic protection, reflecting our selection bias for the use of the Guardwire (Table V). Mean serum creatinine was unchanged at follow-up for the group as a whole as well as the protected and unprotected subgroups. By Kaplan-Meier life-table analysis, 76% of patients exhibited stable or improved creatinine at 1-year follow-up (Fig 2). At last follow-up, renal function was improved in 23%, stable in 53%, and worse in 24%.

**Restenosis.** Follow-up duplex data were available for 78 (92%) of 85 patients. By duplex criteria, restenosis was present in 25% at 1 year (Fig 3). Restenosis was symptomatic in 6 patients (7.7%) at a median of 160 days. These

**Table IV.** Blood pressure and antihypertensive medications (mean  $\pm$  SD) at baseline and at a mean follow-up of 1 year after renal angioplasty and stenting according to indication for treatment

	<i>Baseline</i>	<i>Follow-up</i>	<i>P</i>
HTN ( <i>n</i> = 42)			
Systolic BP (mm Hg)	171 $\pm$ 32	144 $\pm$ 24	<.001
Diastolic BP (mm Hg)	88 $\pm$ 19	76 $\pm$ 9	<.001
Meds (No.)	3.0 $\pm$ 1.1	2.1 $\pm$ 1.2	<.001
CRI ( <i>n</i> = 32)			
Systolic BP (mm Hg)	155 $\pm$ 26	148 $\pm$ 25	.3
Diastolic BP (mm Hg)	79 $\pm$ 12	72 $\pm$ 8	.006
Meds (No.)	3.0 $\pm$ 1.2	2.4 $\pm$ 0.9	.01

HTN, Hypertension; BP, blood pressure; CRI, chronic renal insufficiency; NS, not significant.

patients underwent successful repeat angioplasty, with clinical improvement and without complications. Two asymptomatic patients, one with a solitary kidney and one with duplex evidence of a progressive worsening restenosis, underwent repeat arteriogram and angioplasty. Primary freedom from reintervention (all treated for clinically significant restenosis) was 90% at 1 year. There was no difference in restenosis between the hypertension and CRI groups.

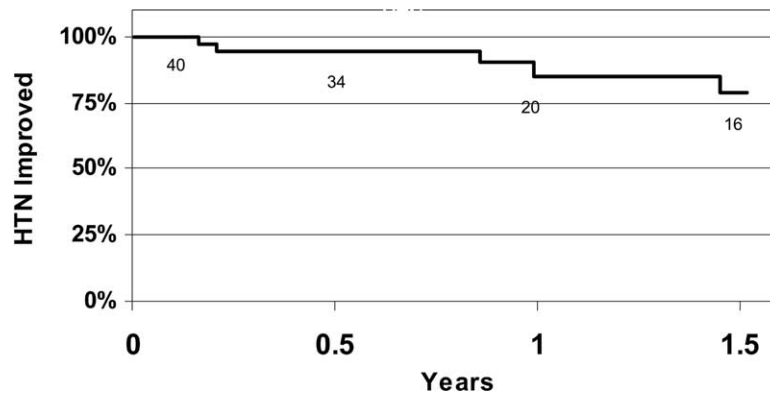
## DISCUSSION

The potential advantage of lower profile systems in renal PTA/RAS is to facilitate technical success and reduce complications. In this series, all but one lesion could be crossed and treated with the 0.014-in or 0.018-in guidewires. Overall technical success was 98%. Major adverse clinical events occurred in 6.1% of patients in the current series. This compares favorably with other reports, even though learning-curve patients were included in this series. In a meta-analysis of RAS and RPTA, major complications (excluding hematomas and puncture trauma) were seen in 11% of cases.<sup>5</sup> Beek et al<sup>16</sup> reported serious adverse events in 10% of their patients and found a similar rate in a review of 13 series. Most major complications were related to wire or catheter trauma. These included retroperitoneal hematomas, both secondary to femoral artery access and wire perforation of the kidney, renal artery dissection, perforation, pseudoaneurysm, thrombosis, aortic atheroemboli, operative conversions, and death.

The lower rates of major complications reported in the current series with low-profile systems appear to be due to fewer traumatic complications. In the current series, there was one traumatic complication, a perinephric hematoma (diagnosed by CT scan) presumably secondary to wire perforation of the kidney, which resolved without operative intervention. Since this case, we have changed to a 0.018-in wire with a shorter, softer tip that allows for stent deployment with less wire in the renal artery.

Most of the major adverse events in this series were renal insufficiency or failure. In 2 of these 3 cases, elevation in serum creatinine was transient and resolved within 30 days. In some series, such cases are often not even reported





**Fig 1.** Proportion of patients with improvement in hypertension (HTN) after renal percutaneous transluminal angioplasty/stenting according to indication for treatment (Kaplan-Meier method, standard error less than 10% throughout, number of patients at risk included with curve).

**Table V.** Change in serum creatinine level (mean  $\pm$  SD) at mean follow-up of 1 year for patients with baseline chronic renal insufficiency with and without embolic protection

	Baseline	Follow-up	P
Total (N = 38)	2.1 $\pm$ 0.9	2.1 $\pm$ 1.0	NS
Embolic protection (n = 16)	2.2 $\pm$ 0.9	2.2 $\pm$ 0.6	NS
No protection (n = 22)	1.9 $\pm$ 0.8	2.1 $\pm$ 1.1	NS

NS, Not significant.

as procedural complications. It is unclear whether these complications in our patients were related to renal atheroemboli during cannulation or were contrast induced. Embolic protection was not used in any of the cases in which this complication occurred. On the basis of previous reports, one would expect the incidence of contrast-induced azotemia to be approximately 2% to 5%.<sup>20</sup>

The incidence of minor complications in the current series is very low, 1.2%, with the single event being a groin hematoma. Minor adverse events occurred in approximately 11% of the cases Beek reviewed; most were access-site hematomas. By using a micropuncture technique, access can be confirmed before introducing larger sheaths. This practice has likely helped minimize groin complications. Likewise, the use of small-diameter guiding catheters (6F instead of 8F) reduces the overall size of the arterial puncture and promotes more successful hemostasis after catheters and sheaths are removed. We routinely used the 6F Perclose (Abbott Vascular) closure device, when appropriate. Although failures occurred that required groin compression, no groin complications related to the Perclose occurred in our patients undergoing RPTA/RAS.

Early results (mean follow-up of 1 year) indicate that clinical outcomes are comparable to studies that used larger profile systems.<sup>5,9,10</sup> In the meta-analysis, hypertension was cured or improved in 69% (39% to 73%) at a mean follow-up of 16-months (6 to 48 months), whereas 89% were

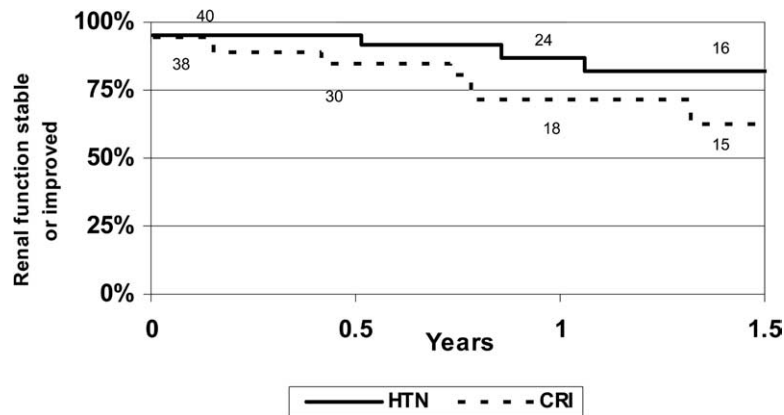
improved in the current series.<sup>5</sup> For patients with CRI, renal function was improved in 30%, stabilized in 38%, and worse in 32% in the meta-analysis; whereas in our series, renal function was improved in 23%, stable in 53%, and worse in 24%. Others have noted similar reductions in medication requirement and blood pressure, as well as stabilization of creatinine.<sup>5,6,21</sup>

In the current series, the Guardwire embolic protection device was used selectively in patients with significantly elevated creatinine or a solitary kidney (or both). The practical advantage of the Guardwire is its low, 0.014-in crossing profile, which is the lowest of the commercially available embolic protection devices. Henry et al reported the feasibility and safety of embolic protection in a series of 32 renal artery interventions.<sup>22</sup>

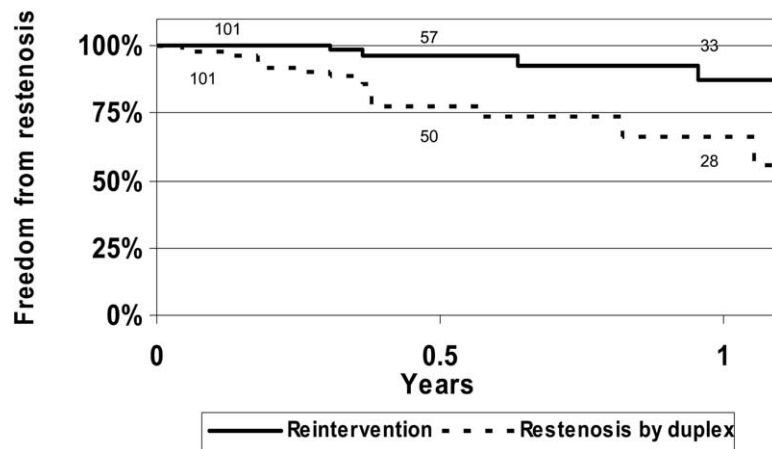
No controlled studies have been performed evaluating the value of embolic protection during endovascular renal intervention. The current study was not designed to address this question, and the overall number of patients studied was too small to allow for comparison. Our initial experience lends support to the assertion that embolic protection can be performed safely and does not appear to worsen short-term outcomes. Anecdotally, large particles of atherosclerotic debris have been retrieved on several occasions. However, more data are needed to determine if the additional cost of these devices is warranted.

Restenosis based on duplex criteria was high—25% at 1 year by life-table analysis. We are currently investigating our relatively high rate of restenosis. Our laboratory is certified by the Intersocietal Commission for the Accreditation of Vascular Laboratories, and we are very confident of the pretreatment studies. Some have suggested that stents in the carotid artery change the duplex criteria and that normal criteria overestimate the frequency of restenosis. We are planning to investigate this for renal arteries.

The ultrasound criteria used to detect restenosis were a PSV of 180 and a RAR of 3.5. These are more stringent criteria than that used for initial screening (200 or 3.5). We



**Fig 2.** Proportion of patients with stabilization or improvement in renal function after renal percutaneous transluminal angioplasty/stenting according to indication for treatment (Kaplan-Meier method, standard error less than 10% throughout, number of patients at risk included with curves). *HTN*, hypertension; *CRI*, chronic renal insufficiency.



**Fig 3.** Freedom from duplex-detected restenosis and clinically significant restenosis requiring re-intervention (Kaplan-Meier method, standard error less than 10% throughout, number of patients at risk included with curves).

used the more stringent criteria for two reasons. First, for comparison to historical controls, the one article that looked critically at duplex restenosis (Yutan<sup>9</sup>) used the same criteria of 180 and 3.5. Second, we wanted to capture patients with ‘early’ restenosis.

All patients had initial (1 month) postoperative duplex scans with normal, low velocities. We believe that an elevation to 180 cm/sec, given a prior normal velocity, represents stenosis. Most of our patients captured in this restenosis group are probably “early,” as only 10% were symptomatic and required repeat arteriogram and PTA.

Although the discrepancy between duplex findings of recurrent stenosis and clinical recurrence is difficult to explain, Yutan et al<sup>9</sup> reported similar findings. In their report, less than half of patients with duplex velocities who met the criteria for stenosis developed recurrent symptoms. This may imply an effect of the stent on traditional duplex velocity criteria for renal stenosis, but this remains to be investigated.

In the meta-analysis, overall 1-year restenosis was 17% but ranged from 0% to 39%, depending on the definition of restenosis, length of follow-up, and whether duplex or angiography alone was used.<sup>5</sup> This wide variability underscores the inherent weakness of a meta-analysis for this topic.

The major limitation of this study is that it is a retrospective analysis of a single-center experience with relatively short follow-up. Our comparisons are based on historical controls—series that used 0.035-in systems. This is particularly true for the evaluation of embolic protection. We plan to continue our practice of selective protection based on the presence of atherosclerotic debris that is often seen in the renal artery aspirate.

Many factors influence the technical success and complication rates with percutaneous interventions, including patient selection and the prior experience of the physicians performing the procedures. The benefit of this report is that it represents the entire experience of RPTA/RAS by a group of vascular surgeons who used a well-defined, uni-

form technique. The group did have extensive experience with percutaneous intervention in other arterial beds prior to performing RPTA/RAS.

In summary, RPTA/RAS with low-profile systems may reduce complication rates and improve technical success, even during the learning curve of developing expertise in renal artery PTA and stenting. Comparable to previous reports that used larger profile systems, RPTA/RAS with low-profile systems appears to have a better effect on reducing blood pressure and medication requirements, and a similar effect on renal function in patients with CRI. Embolic protection offers theoretical advantages; however, longer follow-up is needed to determine the effectiveness of these systems. Although restenosis rates by duplex criteria are high and comparable with previous reports, almost all of the patients maintained clinical benefit and those with clinically significant restenosis could usually be managed successfully with repeat angioplasty or stenting.

## REFERENCES

1. Gruntzig A, Kuhlmann U, Kaufman S. Treatment of renovascular hypertension with percutaneous transluminal dilatation of a renal artery stenosis. *Lancet* 1978;1:801-2.
2. Katzen B, Chang J, Lukowsky G, Abramson E. Percutaneous transluminal angioplasty for the treatment of renovascular hypertension. *Radiology* 1979;131:53-8.
3. Tegtmeyer C, Kellum C, Ayers C. Percutaneous transluminal angioplasty of the renal artery. Results and long-term follow-up. *Radiology* 1984;153:77-84.
4. Weibull H, Tornquist C, Bergqvist D, Nyman U, Takolander R, Karlsson S, et al. Reversible renal insufficiency after percutaneous transluminal angioplasty (PTA) of renal artery stenosis. *Acta Chir Scand* 1984;150:295-300.
5. Leertouwer TC, Gussenhoven EJ, Bosch JL, van Jaarsveld BC, van Dijk LC, Deinum J, et al. Stent placement for renal arterial stenosis: where do we stand? A meta-analysis. *Radiology* 2000;216:78-85.
6. Lederman R, Mendelsohn F, Santos R, Phillips H, Stack R, Crowley J. Primary renal artery stenting: characteristics and outcomes after 363 procedures. *Am Heart J* 2001;142:314-23.
7. Bakker J, Goffette P, Henry M, Mali WP, Melki JP, Moss JG, et al. The Erasme study: A multicenter study on the safety and technical results of the Palmaz Stent used for the treatment of atherosclerotic ostial renal artery stenosis. *Cardiovasc Intervent Radiol* 1999;22:468-74.
8. Gill K, Fowler R. Atherosclerotic renal arterial stenosis: clinical outcomes of stent placement for hypertension and renal failure. *Radiology* 2003;226:821-826.
9. Yutan E, Glickerman DJ, Caps MT, Hatsukami T, Harley JD, Kohler TR, et al. Percutaneous transluminal revascularization for renal artery stenosis: Veterans Affairs Puget Sound Health Care System experience. *J Vasc Surg* 2001;34:685-693.
10. Bush R, Najibi S, MacDonald M, Lin PH, Chaikof EL, Martin LG, et al. Endovascular revascularization of renal artery stenosis: technical and clinical results. *J Vasc Surg* 2001;33:1041-9.
11. van de Ven PJ, Kaatee R, Beutler JJ, Beek FJ, Woittiez AJ, Buskens E, et al. Arterial stenting and balloon angioplasty in ostial atherosclerotic renovascular disease: a randomised trial. *Lancet* 1999;353:282-286.
12. Cognet F, Garcier JM, Dransart M, Defraissinet B, Cercueil JP, Ravel A, et al. Percutaneous transluminal renal angioplasty in atheroma with renal failure: long-term outcomes in 99 patients. *Eur Radiol* 2001;11:2524-2530.
13. Weibull H, Bergqvist D, Bergentz S-E, Jonsson K, Hulthen L, Manhem P. Percutaneous transluminal renal angioplasty versus surgical reconstruction of atherosclerotic renal artery stenosis: A prospective randomized study. *J Vasc Surg* 1993;18:841-52.
14. Watson PS, Hadjipetrou P, Cox SV, Piemonte TC, Eisenhauer AC. Effect of renal artery stenting on renal function and size in patients with atherosclerotic renovascular disease. *Circulation* 2000;102:1671-7.
15. Harden PN, MacLeod MJ, Rodger RS, Baxter GM, Connell JM, Dominiczak AF, et al. Effect of renal-artery stenting on progression of renovascular renal failure. *Lancet* 1997;349:1133-6.
16. Beek FJ, Kaatee R, Beutler JJ, van der Ven PJ, Mali WP. Complications during renal artery stent placement for atherosclerotic ostial stenosis. *Cardiovasc Intervent Radiol* 1997;20:184-90.
17. Rundback JH, Sacks D, Kent KC, Cooper C, Jones D, Murphy T, et al. Guidelines for the reporting of renal artery revascularization in clinical trials. *J Vasc Intervent Radiol* 2002;13:959-74.
18. Rundback JH, Sacks D, Kent KC, Cooper C, Jones D, Murphy T, et al. Guidelines for the reporting of renal artery revascularization in clinical trials. *Circulation* 2002;106:1572-85.
19. Olin JW, Piedmonte MR, Young JR, DeAnna S, Grubb M, Childs MB. The utility of duplex ultrasound scanning of the renal arteries for diagnosing significant renal artery stenosis. *Ann Intern Med* 1995;122:833-8.
20. Baker CSR, Wragg A, Kumar S, De Palma R, Baker LRI, Knight CJ. A rapid protocol for the prevention of contrast-induced renal dysfunction: the RAPPID study. *J Am Coll Cardiol* 2003;41:2114-8.
21. Dorros G, Jaff M, Mathiak L, He T. Multicenter Palmaz stent renal artery stenosis revascularization registry report: four-year follow-up of 1,058 successful patients. *Catheter Cardiovasc Interv* 2002;55:182-188.
22. Henry M, Amor M, Henry I, Etchevenot G, Tzvetanov K, Courvoisier A, et al. Stents in the treatment of renal artery stenosis: long-term follow-up. *J Endovasc Surg* 1999;6:42-51.

Submitted May 29, 2004; accepted Oct 17, 2004.

## The JVS Ombudsman

The ombudsman's role is to act as an advocate for authors and represent their position to the editorial staff in relation to the process of manuscript submission, review, and publication. The ombudsman is *not* responsible for evaluating the content of a manuscript or determining whether the editors made the correct decision with regard to acceptance or rejection of the paper. If an author or other person has an unresolved complaint or question about the editorial process of the Journal, he or she should contact Dr James S. T. Yao (Northwestern University Medical School, Department of Surgery, 201 E. Huron Street, Suite 10-105, Chicago, IL 60611), who will review the matter.